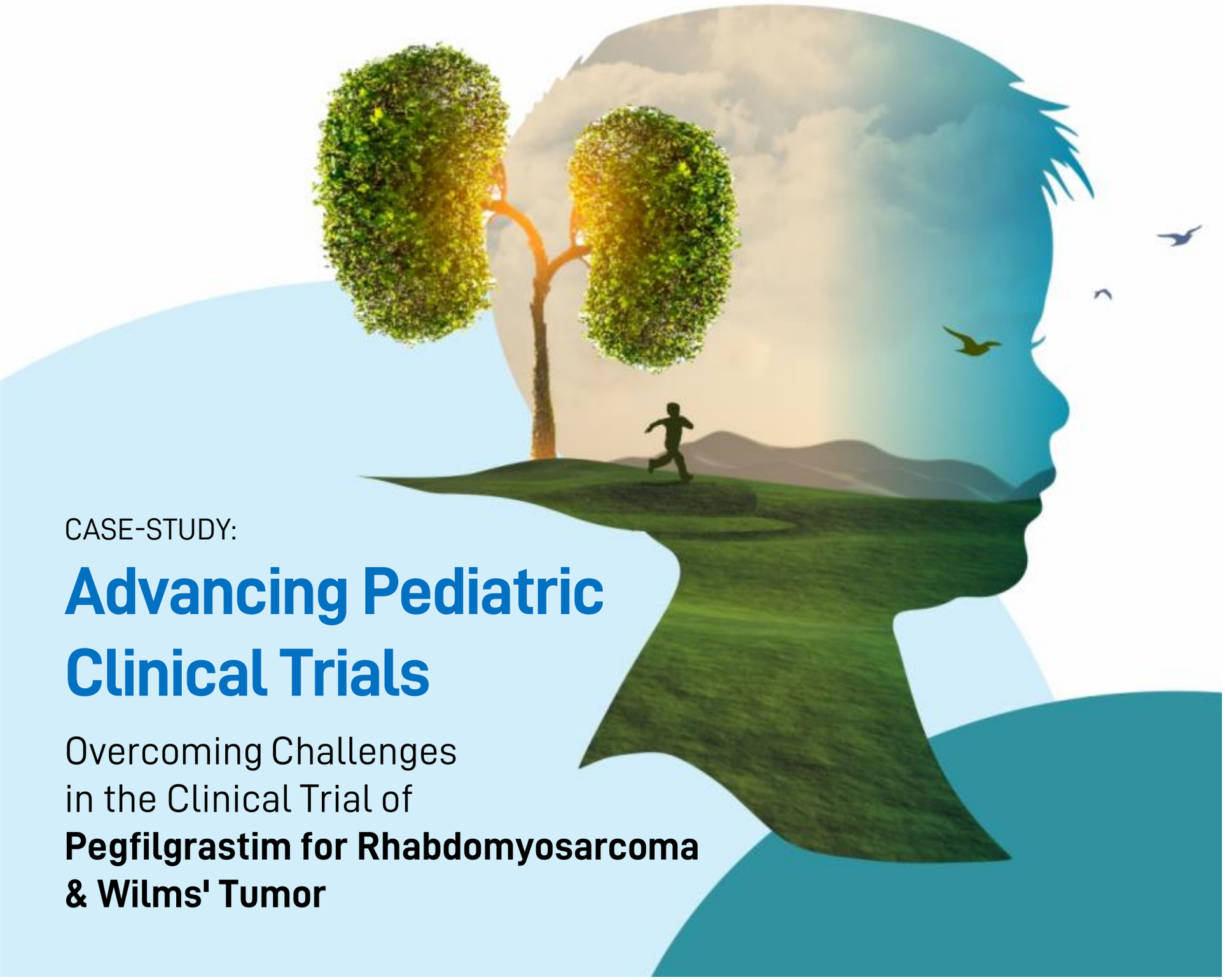
LAMBDA
Research Accelerated

Novum
PHARMACEUTICAL RESEARCH SERVICES



CASE-STUDY:

Advancing Pediatric Clinical Trials

Overcoming Challenges
in the Clinical Trial of
Pegfilgrastim for Rhabdomyosarcoma & Wilms' Tumor

Study Overview:

Pegfilgrastim, a drug with proven efficacy in adults, was investigated in pediatric patients. Although studies in adults demonstrated similar efficacy to filgrastim, limited data existed for the pediatric population, specifically in rhabdomyosarcoma and Wilms' tumor patients.

Study Design:

A randomized active-controlled multicenter open-label two-arm study was designed to assess the safety, efficacy, pharmacodynamics, and pharmacokinetics of Pegfilgrastim PFS in comparison to the Reference Product in pediatric participants under 6 years old with rhabdomyosarcoma or Wilms' tumor.

Challenges and Solutions:

Challenges	Solutions
Recruitment of Pediatric Patients:	
• Difficulty in identifying and recruiting pediatric patients (0 to 6 years old) with rhabdomyosarcoma or high-risk Wilms' tumor which are **rare indications** in pediatric oncology. • Requirement for patients on **specific chemotherapy ranges**, limiting the pool of eligible participants • **Patient retention for 90 days**	• Identified investigator sites with substantial patient pools and extensive clinical trial experience, including government sites to enhance recruitment efforts.
Dosing and IMP Management	
• Dosing calculation complexity due to the pediatric population and the need to finalize doses based on weight, resulting in very small IMP doses compared to the market-available doses.	• Close oversight of IMP dosing, providing specialized dose calculation tables and 1 ml Tuberculin syringes to enhance dosing accuracy for the pediatric population. • A dedicated, trained, and experienced team of Phlebotomists was deployed
Handling of PK & PD Samples:	
• Sensitivity in handling PK & PD samples in the pediatric population, with the risk of mishandling leading to the loss of samples	• Conducted comprehensive training and continuous guidance for the site staff regarding dosing procedures, PK samples handling, and other critical aspects of the study.

LAMBDA
Research Accelerated

Novum
PHARMACEUTICAL RESEARCH SERVICES

Achievements:

- Successfully randomized **12 pediatric patients** within an impressive **7-month period**, showcasing effective patient enrollment strategies.
- Executed the trial efficiently within **a timeline of 12 months**, from the first site initiation visit (SIV) to the last patient's last visit, meeting the study's objectives and timelines for EMEA submission compliance.

Leverage Lambda & Novum's extensive experience & proven track record to accelerate your Pediatrics clinical trials. Get in touch with our team of experts.

Email: **BD@lambda-cro.com**

Lambda Therapeutic Research Ltd.
www.lambda-cro.com

Novum Pharmaceutical Research services
www.novumprs.com

India | USA | Canada | UK | Poland